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Secretary of the Commission
U. S. Nuclear Regulatory Commission
Docketing & Service Branch, Docket #PRM-35-9
Washington, D.C. 20555

Dear Mr. Secretary:

The Petition for Rule making filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine is of vital importance to the patients who are receiving and may in the future require nuclear medicine consultation and services. The revision of 10CFR35 regulations governing the medical use of by product materials in patients has compromised my and my fellow nuclear medicine practitioners' ability to provide the optimum in quality care.

By being required to strictly adhere to the Manufacturer's restrictions, i.e., the package insert in radiopharmaceuticals, the latitude granted other practicing physicians has been markedly curtailed. The NRC should recognize, as does the FDA, that appropriately licensed physicians by virtue of their professional training and competence must be able to select optimum approaches to apply approved drugs (radiopharaceuticals) in a manner befitting patient requirements to obtain beneficial objectives of diagnostic and/or therapeutic procedures. Present regulatory provisions in Part 35 (35.100, 35.200, 35.300, and 33.17(a)(4) preclude practices which are legitimate, legal and reasonable under FDA regulations, as well as State Statutes governing the practice of medicine and pharmacy. By these regulations the Commission is inappropriately interfering with the practice of medicine to the detriment of quality patient care. A fact which directly contradicts the NRC's Policy statement against interference with the practice of medicine.

The unnecessary restriction of a physician's ability to exercise professional judgment in selecting the optimum diagnostic or therapeutic approach to the individual patient will, in my opinion, have a greater likelihood of jeopardizing public and patient health and safety. By requiring the selection of alternate approaches which will in a majority of cases result in higher radiation dose as well as greater potential for morbidity and mortality, the patient will be less well served.

The NRC should cease the progressive evolution of proscriptive regulations intruding into the practice of medicine. It should

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instead accept the existing body of regulations and statutes which have governed the practice of medicine and pharmacy, i.e., the FDA, State Boards of Pharmacy and Medicine, the Joint Commission on Accreditation of Health Care Organizations. Key to the optimum in patient care and the outcome related to physician-patient professional practice interaction is the ability to exercise professional judgment in the individual patient's case. In a similar fashion the qualified pharmacists preparing the prescribed radiopharmaceuticals must be allowed latitude in preparation and compounding under appropriate practice of pharmacy provisions. Training and educational programs are in place for practitioners in the field of Nuclear Medicine, along with mechanisms for continuing education in a fashion analogous to other disciplines of medicine and pharmacy. The current NRC regulations represent an aberration from the contemporary practices and procedures governing medicine and pharmacy.

I request that the NRC adopt the ACNP/SNM Petition for Rule making in order to restore the quality of patient care provided by allowing the practitioner appropriate latitude in decision making for individual patient care.

Respectfully submitted,

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